

REMARKS

Claims 4, 9, 13, 17, 21, 25-42, 44, 46, 47, 82-91, and 93-111 were pending and examined in the July 28, 2004 office action. Claims 46, 47, 107, and 108 are cancelled without prejudice herein. Claims 4, 26-42, 82-88, 100, 101, and 111 have been amended to clarify that which the Applicant regards as his invention. Support for the amendments to claims 4, 26-42, 82-88, 100, 101, and 111 can be found throughout the specification as filed. In particular, support for the amendments to claims 4, 26-42, 82-88, 100, 101, and 111 can be found in the specification at page 8, lines 14-24. Thus, claims 4, 9, 13, 17, 21, 25-42, 44, 82-91, 93-106, and 109-111 will be pending upon entry of the amendments made herein.

INTERVIEW SUMMARY

Applicant and Applicant's representatives thank Examiner Christopher H. Yaen and the Examiner's supervisor Jeffrey Siew for the courtesy of the in-person interview of December 14, 2004 in connection with the above-identified application. Pursuant to MPEP section 713.04, Applicant submits the following statement of the substance of the interview between Examiner Yaen and Supervisor Siew, Applicant's representatives Adriane M. Antler and Christine B. Chua, and the Applicant, Dr. Pramod K. Srivastava.

During the interview, the rejections set forth in the Office Action dated July 28, 2004 were discussed. Discussed were the written description and enablement rejections under 35 U.S.C. § 112, first paragraph, and the prior art anticipation and obviousness rejections under 35 U.S.C. §§ 102(b) and 103.

In a discussion regarding the written description and enablement rejections, Dr. Antler stated that the claims would be amended to delete the terms "inhibiting" and the term "vaccine". Examiner Yaen agreed that the foregoing claim amendments would obviate the § 112 rejections.

Regarding the outstanding anticipation and obviousness rejections over Chen *et al.*, Dr. Antler pointed out that Chen *et al.* does not anticipate the pending claims since Chen *et al.* teaches administration of DNA compositions such as 1) HSP70 DNA; 2) E7 DNA; 3) E7-HSP70 DNA; or 4) E7 DNA mixed with HSP70 DNA. In contrast, the claimed invention specifies administration of a heat shock protein preparation (in addition to administration of the composition comprising a component that displays the antigenicity of a

cancer cell) which necessarily comprises a protein, and more specifically a heat shock protein. Since Chen *et al.* does not teach administration of a heat shock *protein* preparation in combination with the specified composition, Chen *et al.* does not anticipate.

Furthermore, Dr. Antler pointed out that the claimed invention is not obvious over the teaching of Chen *et al.* In fact, Chen *et al.* teaches away from the claimed invention. Pointing to Figures 1A and Figure 5 of Chen *et al.*, Dr. Antler reviewed Figure 1 which demonstrates that when administered to a mouse, an E7-HSP70 DNA fusion, but not a mixture of E7 DNA and HSP70 DNA, results in an enhanced E7-specific CD8+ T-cell mediated immune response. In addition, in a tumor protection context, Figure 5 showed that all mice vaccinated with E7-HSP70 DNA remained tumor free 60 days after tumor challenge, while all the mice vaccinated with E7 DNA mixed with HSP70 DNA developed tumor growth within 15 days after the tumor challenge. Thus, one of skill in the art would have no motivation to use unbound HSP DNA, much less be motivated to use unbound HSP on a protein level. In addition, Chen *et al.* does not suggest administration of an HSP DNA fused to a DNA that does not display the immunogenicity of the component, and logically does not suggest the administration of an HSP bound to a molecule that does not display the immunogenicity of the component. In addition, Dr. Antler emphasized Chen *et al.*'s focus on DNA vaccines, pointing to page 1039 of the Chen *et al.* reference, right column, first full paragraph, where the authors contrast the differences between their findings using "DNA-based" HSP vaccines and the findings of others using "protein-based HSP-containing vaccines."

**THE WRITTEN DESCRIPTION REJECTION UNDER 35 U.S.C. § 112,
FIRST PARAGRAPH SHOULD BE WITHDRAWN**

The Examiner rejected claims 4, 9, 13, 17, 21, 25-42, 44, 47, 82-91, 93-111 under 35 U.S.C. § 112, first paragraph, as lacking written description, in the recitation of "inhibiting" cancer. As discussed during the interview, the claims have been amended to delete the phrase "inhibiting." Applicant submits that as agreed in during the in-person interview, the foregoing amendment obviates the Examiner's rejection. Applicant respectfully requests withdrawal of the written description rejection.

**THE ENABLEMENT REJECTION UNDER 35 U.S.C. § 112,
FIRST PARAGRAPH SHOULD BE WITHDRAWN**

The Examiner rejected claims 4, 9, 13, 17, 21, 25-42, 44, 47, 82-91, and 93-111 under 35 U.S.C. § 112, first paragraph as not enabled. As suggested by Examiner Yaen in the outstanding office action, the claims have been amended to delete the phrase “vaccine.” Applicant submits that as discussed in during the in-person interview, the foregoing amendments obviate the Examiner’s enablement rejection. Applicant respectfully request withdrawal of the enablement rejection.

**THE ANTICIPATION REJECTION UNDER
35 U.S.C. § 102 SHOULD BE WITHDRAWN**

The Examiner rejected claims 4, 9, 13, 27, 30, 33, 42, 44, 46, 82, 86, 90, 93, 94, 95, 97, 100, 101, 107 and 111 under 35 U.S.C. § 102, as anticipated by Chen *et al.* Chen *et al.* does not anticipate the pending claims since Chen *et al.* teaches administration of DNA compositions such as 1) HSP70 DNA; 2) E7 DNA; 3) E7-HSP70 DNA; or 4) E7 DNA mixed with HSP70 DNA. In contrast, the claimed invention specifies administration of a heat shock protein preparation (in addition to administration of the composition comprising a component that displays the antigenicity of a cancer cell) which necessarily comprises a protein, and more specifically a heat shock protein. Since Chen *et al.* does not teach administration of a heat shock *protein* preparation in combination with the specified composition, Chen *et al.* does not anticipate. As discussed during the interview and as summarized above, the teaching of Chen *et al.* does not deprive the current claims of novelty.

Applicant submits that the foregoing remarks, summarized above and now of record, obviate the Examiner’s anticipation rejection, and respectfully requests its withdrawal.

**THE OBVIOUSNESS REJECTION UNDER
35 U.S.C. § 103 SHOULD BE WITHDRAWN**

The Examiner rejected claims 4, 9, 33, 42, 44, 46, 82, 86, 90, 94, 95, and 97 under 35 U.S.C. § 103, as obvious over the disclosure of Chen *et al.* The claimed invention is not obvious over the teaching of Chen *et al.* In fact, Chen *et al.* teaches away from the claimed invention. Figure 1 of Chen *et al.* demonstrates that when administered to a mouse, an E7-HSP70 DNA fusion, but not a mixture of E7 DNA and HSP70 DNA, results in an enhanced E7-specific CD8+ T-cell mediated immune response. In addition, Figure 5 of Chen *et al.* shows that in a tumor protection context, mice vaccinated with E7-HSP70 DNA remained

tumor free 60 days after tumor challenge, while all the mice vaccinated with E7 DNA mixed with HSP70 DNA developed tumor growth within 15 days after the tumor challenge. Thus, one of skill in the art would have no motivation to use unbound HSP DNA, much less be motivated to use unbound HSP on a protein level. In addition, Chen *et al.* does not suggest administration of an HSP DNA fused to a DNA that does not display the immunogenicity of the component, and logically does not suggest the administration of an HSP bound to a molecule that does not display the immunogenicity of the component. In addition, Chen *et al.*'s focus is on DNA vaccines. See page 1039 of the Chen *et al.* reference, right column, first full paragraph, where the authors contrast the differences between their findings using "DNA-based" HSP vaccines and the findings of others using "protein-based HSP-containing vaccines."

For the foregoing reasons and as discussed during the in-person interview, the current claims are not obvious in view of the teaching of Chen *et al.* Applicant submits that these arguments of record obviate the Examiner's obviousness rejection, and respectfully requests withdrawal of the rejection.

For all the reasons set forth in the amendments and remarks filed on May 3, 2004, December 23, 2003 and September 10, 2003, and as discussed in the December 14, 2004 in-person interview and summarized herein, Applicant submits that the Examiner's rejections have been obviated and respectfully requests their withdrawal.

Applicant respectfully requests that the Examiner reconsider this application with a view towards allowance. The Examiner is invited to call the undersigned attorney at (212) 326-3630, if a telephone call could help resolve any remaining issues.

Respectfully submitted,

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